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Chapter 4

Implementation of Quality Control

Irfan Ahmad

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Abstract

Quality control is a procedure for examining the problems, work processes as well as making improvements preceding to transport of products. In the global markets, the rising competition between manufacturers and producers has guided firms in recognizing the competitive benefits. However, in the previous eras, the importance has been attentive on the continuous upgrading of quality for the success of several kinds of business in present and future. Employing a universal quality assurance background will help in more effective organization and improve the quality of statistical output in international organizations. Quality values are an essential part of the quality system. They are deliberated to support regulatory requirements of the laboratories, including monitor laboratory functions and local health regulations, thus confirming the safety of the local health regulations and reliability of performance. This chapter highlights the elements essential for effective implementation of quality control.

Keywords: quality control, implementation, essential elements, quality management, improvement, six sigma

1. Introduction

Quality is a worldwide value and now has converted a universal concern. The burden of globalization has built manufacturing organizations affecting to three main competitive areas such as cost, responsiveness and quality. For the better survival, it is necessary to offer clienteles with good quality stuff, so necessary for manufacturing organizations to ensure that their procedures are constantly supervised and quality of the product is enhanced. The manufacturing company applies several techniques for quality control (QC) to increase the quality of the progression by decreasing its variability [1].

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A variety of methods exist to control the products or process quality. Seven statistical process control (SPC) tools are included such as plan, do, check, act (PDCA), quality function deployment (QFD), acceptance sampling, failure mode and effects analysis (FMEA), a design of experiments (DoE) and six sigma [2]. This chapter emphasizes the implementation of quality control in companies and categorizes the factors applying for quality control techniques, the techniques used in the implementation. The inspiring factors for the companies to relate quality control and tasks challenge by companies in implementing the quality control [3–5].

Laboratory facilities are an important constituent of quality health care. It can be employed efficiently at each level of health care system, involving point-of-care and primary health care testing. Results of the quality laboratory are requisite to support justify, monitor, treatment and clinical diagnosis, for the purposes of epidemiology, surveillance and control of disease at public health importance, and to deliver the initial warning of disease epidemics. This increases the accuracy of health evidence and endorses the national health planning effectively. The aim of establishing laboratory quality standards is to confirm the confidence of patients, increase the accuracy of test results, communities and clinicians in the importance of laboratory testing, and to update patient management [6]. Entirely laboratory activities might be subject to errors, and many studies have exposed that errors in the laboratory can appear in all the phases of diagnostic processes. The examples of errors that may occur in all phase are given below.

1.1. Pre-analytical phase

- Incorrect test selection or test request
- Incomplete request forms of laboratory
- Incorrect collection of specimen, inadequate quantity, improper labeling and transportation

1.2. Analytical phase

- Use of defective equipment, inappropriate use of an equipment
- Use of expired or substandard reagents
- Incorrect storage and reagent preparation
- Incorrect procedures; non-adherence to internal quality control (IQC) or standard operating procedures (SOPs)

1.3. Post-analytical phase

- Inappropriate reporting or recording
- Incorrect calculations, transcription or computation
- Send the results too late to the clinician
- Inappropriate interpretation of the results

2. Quality control

Quality can be described as achieving customer requirement or specification, without any deficiency. A product is considered to be great in quality if it is working as reliable and expected. Quality control denotes to activities to confirm that produced articles are achieving the highest promising quality. Furthermost of tools and techniques to control the quality are statistical procedures. The techniques for the quality control can be categorized into the basic, intermediate and advanced level, although there is no unanimity amongst researchers about it. For example, Xie et al. [7] deliberate the DoE as an intermediary level technique while Antony et al. [8] classified that technique as advanced. Nonetheless, the contents are more significant rather than the classification. Amongst the basic techniques, SPC is a statistical method for supporting the supervisors, operators and managers to accomplish quality and to remove special causes of inconsistency in the process [9]. The early role of SPC is to stop rather than process deterioration or recognize the product, but Xie et al. [7] propose for its new role to vigorously identifying prospects for the improvement of the process. The foremost tools in SPC are control charts. An essential knowledge of the control charts is to analyze the hypothesis that there are few common reasons of alternative versus variability, that there are exceptional causes by continuously observing the process. The manufacturing company could avoid defect items to be administered in the subsequent stage and to take instant corrective action while the process exists to be out of control [10].

DoE and Taguchi approaches are influential tools for the development of product and process. Taguchi methods, for example, the purpose of manufacturing products or process that vigorous to non-desirable turbulences such as manufacturing and environmental variations. Though, the request of these two approaches by industries is inadequate [11]. Antony et al. [8] delineate the problems in the application including the inappropriate understanding of statistical ideas in the procedures; therefore recommend an approach for the implementation. Procedure ability study is an effective technique to examine the ability of a procedure to produce items that meet specifications.

The process gains fast raising attention because of increased utilization of the quality system (QS9000), where to take advantage of method capability study are demanded [12]. The outcome obtains from capability study may want some modification of process employing some other statistical technique, for example, DoE or SPC. Furthermore, Motorcu and Gullu [13] and Srikaeo et al. [14] conducted a capability study in which process capability production and stability machine tool were assessed and crucial procedure to diminish poor quality production was carried out employing other statistical methods.

Failure mode and effects analysis (FMEA) is a well-known technique to identify the point where precisely problems can take place as well as to urgencies feasible problems in the order of their difficulty [15]. This tool is valuable to troubleshoot problems in the process, i.e. process FMEA and to recognize problems in the product, i.e. design FMEA [7]. Additionally, six sigma is also a known statistical device for confirming the fault-free products via nonstop progress and six sigma application has been chiefly employed in manufacturing industry. However, use of six sigma in the software development is a case of the non-manufacturing

industry [16]. The term six sigma instigated by Motorola as well as various motivated international organizations have fixed goal concerning a six sigma level of implementation [17].

Moreover, acceptance sampling is alternative statistical techniques that concluded whether to take or refuse a quota based on the information from the sample. The request for the approval of sampling permits industries to minimize the product demolition through examination and to raise the inspection capacity and efficiency. The request of getting sampling has been chiefly employed in manufacturing industry; however, Slattery [18] reported its application in non-manufacturing industry.

3. Implementation of the quality control system

Quality standards are an integral part of the quality system. They are designed to help laboratories meet regulatory requirements, including local health regulations, and monitor laboratory functions, thereby ensuring laboratory safety and consistency of performance. A quality system can be developed in a step-wise manner and implementation (**Table 1**).

The methodologies for the implementation of quality control can be differ in diverse organizations. Irrespective the methodologies of the continuous improvement program, each organization desire to use the proper tools and techniques in the process of implementation. The selection of tools and techniques is depend on the demands and applied appropriately to the approach and process.

The PDCA is an essential concept for quality improvement processes, easy to understand and followed by most of the organizations. The most significant characteristic of PDCA lies in the "act" phase after the completion [19]. The six-sigma procedure is consistent and delivers a rigorous outline of results concerned with management. It must be distinguished that the greatest results from six-sigma are accomplished and eradicating unproductive procedures, especially when the members of the team are new to the concerned tools and techniques [20, 21].

3.1. Implementation of laboratory quality standards

The implementation process for laboratory quality standards must follow a stepwise attitude conferring to an implementation strategy drawn up by the national laboratory, in discussion with the National Laboratory Coordinating Committee. Certain countries can desire to progress national laboratory quality standards for all level of health care system.

Implementing laboratory quality standards guidelines are as follows.

3.1.1. National level

1. Achieve nationwide agreement for established standards through peer review.
2. Achieve consent to established standards via the suitable nationwide experts.

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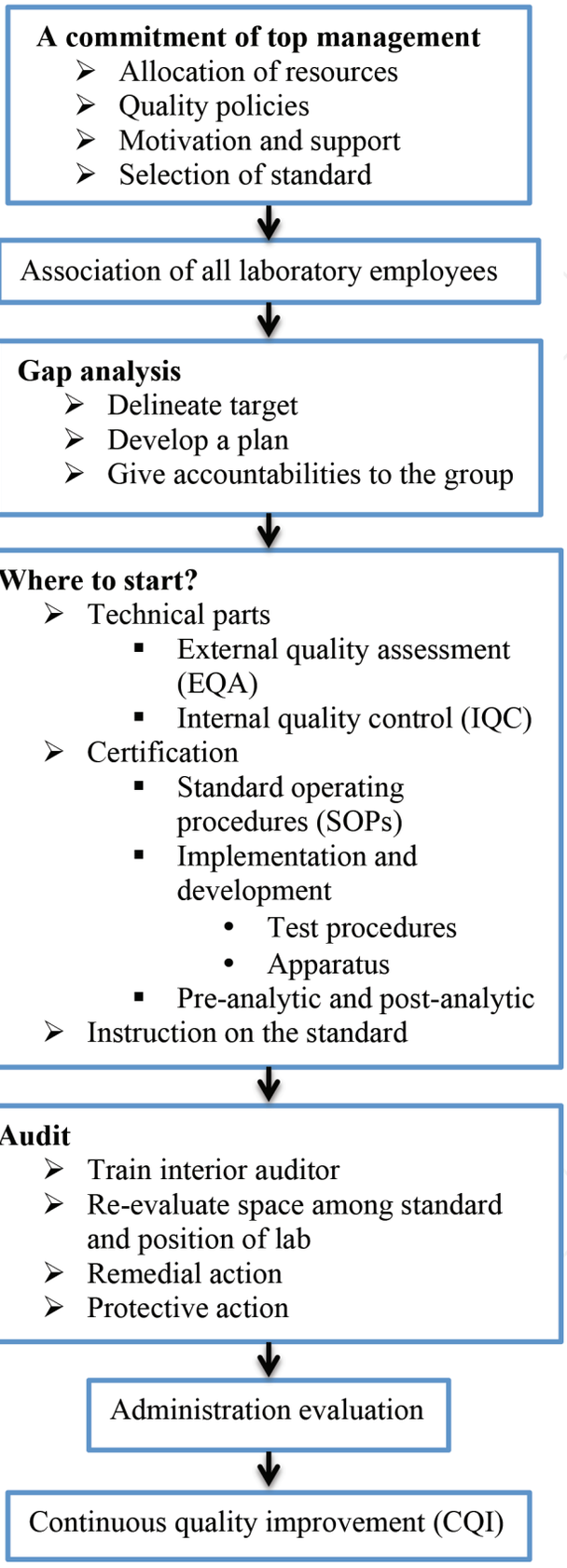


Table 1. Key steps in implementing a quality system.

3. Make a short-term, medium-term and long-term implementation plan for objectives, timelines and activities, and revealing yearly budgets.
4. Recognize suitable implementing agencies such as non-government, governmental agencies, and the private sectors.
5. Explain partaking health facilities and institutions.
6. Use existing SOPs, checklists, record forms, guidelines and appraisal forms, audit checklists, recording formats etc. or develop the documents for the country specific.
7. Establish the national procedures for the referral of samples and laboratory networking.
8. Establish the annual plans with budgets.

3.1.2. Laboratory level

A similar procedure will be mandatory by different laboratories. The head of the laboratory will require taking a leadership role and involving all the staff. Several changes are informal to implement and some are extra expensive or tougher to implement.

The changes that make the implementation of quality control simple and easy:

1. Introduction of SOPs for specific activities or procedures. This can be the collection of the sample, comprising phlebotomy for the investigation of a specific analysis.
2. Arrange meetings with the users consistently. This will inform the users of the service to upgrade the quality of laboratory.

4. Challenges and future trends in QC implementation

Quality control by manual approach could be established in several companies, such as, to observe cuprum pipe pressing procedure, specific control chart is employed to identify the existence of precise distinctions in the process. Furthermore, the chart is made by hand hence it needs a large amount of time period for chart preparation. However, the workers appear found to be more comfy with hard copy records as well as the manual process in making a record for the created items. The absence of confident in soft copy file supposed to be dread that someone may interfere and alter the data that can depreciate the company reputation.

Earlier studies have been showed comparable difficulties in applying quality control between native manufacturing institutes. Among the serious difficulties are concerning insignificant process observing, incapability to accomplish data analysis, the accomplishment of control chart just on the completed products and not in a real-time approach [22, 23]. Additionally, real-time quality control additionally affords countless competence to the management since it takes time to make manual control charts as well as the time permitted to accomplish significant data analysis, is reduced [24]. Study by Mohd Nizam et al. [25, 26] and Rosmaizura et al. [27] show obstacles in developing an online Statistical Process Control (SPC) system

and the outcome of the study illustrate that aspects associated with highest management support, inter-departmental correlation, budgets to improve the system and education on SPC are hindering manufacturing institutes via showing real-time process censoring. It is well documented that strong obligation by top management is very important for the fruitful accomplishment of SPC [28, 29].

In forthcoming days, it is supposed that manufacturers will face a progressively undefined exterior atmosphere through an increasing consequence of alterations in worldwide competition, technological improvement and customer necessities. Flexibility, cost, time and quality are considered as amongst the very significant competitive weaponry for the success of manufacturing companies. Manufacturers face the task of refining the efficacy and lowering prices. Hence, QC techniques would be constantly used to support the organizations to develop, revolutionize their goods and progression in order to be acknowledged by customers. Because of the rising concern on maintainable place and source for the upcoming generation, manufacturers are expected to give more consideration to the environmental effect from their operations. So, application of environment preservation, atmosphere friendly industrial practices and green technology seem to be dominant.

5. Conclusions

All the employees incorporate the concepts for implementation of quality control in a laboratory or organization. That will give massive benefits for the improvement of quality control. Though the program of quality assurance is still independent to monitor the process of quality control. Implementation of QC may require a change during the setup of quality management system. The encouraging features for the companies to concern quality control arise inside from the organization, parental company and/or externally from the customer. The companies use widely SPC and acceptance sampling. DOE, Taguchi methods, Six Sigma, and capability studies are missing to be used by the industries, because of the lack of knowledge in the technique. They fulfill the criteria for the laboratories requirement such as health regulation, consistency in performance, laboratory functions and safety. Three aspects influence the quality control procedure in the firms, such as the capability to quantify product specification contentment; simplicity in the use of the technique; and capability to progress acute characteristic and yield difficulty. Hence QC technique will combine all these environmental concerns like its significant elements and ease and quickness for use would be the probability for QC techniques of the future.

Author details

Irfan Ahmad

Address all correspondence to: Irfancsmmu@gmail.com

Department of Clinical Laboratory Sciences, College of Applied Medical Sciences,
King Khalid University, KSA

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